

ORAL ARGUMENT NOT YET SCHEDULED

No. 24-5294

IN THE
**United States Court of Appeals
for the District of Columbia Circuit**

PUBLIC EMPLOYEES FOR ENVIRONMENTAL RESPONSIBILITY, ET AL.,
Plaintiffs-Appellants,

v.

LEE ZELDIN, ET AL.,
Defendants-Appellees,

INHANCE TECHNOLOGIES LLC,
Intervenor-Appellee.

On Appeal from the United States District Court
for the District of Columbia, No. 24-cv-2194
(James E. Boasberg, C.J.)

BRIEF FOR APPELLEE INHANCE TECHNOLOGIES LLC

J. TOM BOER
HOGAN LOVELLS US LLP
4 Embarcadero Center, Suite 3500
San Francisco, CA 94111
(415) 274-2300
tom.boer@hoganlovells.com

August 29, 2025

JESSICA L. ELLSWORTH
SUSAN M. COOK
MARLAN GOLDEN
J. ANDREW MACKENZIE
HOGAN LOVELLS US LLP
555 Thirteenth Street, N.W.
Washington, D.C. 20004
(202) 637-5600
jessica.ellsworth@hoganlovells.com
Counsel for Inhance Technologies LLC

TABLE OF CONTENTS

	<u>Page</u>
TABLE OF AUTHORITIES	iii
GLOSSARY	viii
INTRODUCTION	1
ISSUES PRESENTED FOR REVIEW	2
PERTINENT STATUTES AND REGULATIONS	3
STATEMENT OF THE CASE.....	3
A. The Toxic Substances Control Act.....	3
B. Inhance’s Fluorination Process	7
C. Litigation Over Inhance’s Fluorination Process Ensues	8
D. EPA’s Initiation Of Section 6 Procedures.....	11
E. The District Court Dismisses The Lawsuit	11
SUMMARY OF ARGUMENT	12
ARGUMENT	15
I. PEER AND CEH LACK STANDING	15
A. Appellants Are Not Membership Organizations And Therefore Do Not Qualify For Associational Standing	16
B. Appellants’ Staff And Supporters Do Not Have Standing In Their Own Right	22
II. EPA IS NOT IN VIOLATION OF A NONDISCRETIONARY DUTY	26
A. There Is No Pending Mandatory Duty Under TSCA Section 6	27
1. <i>EPA Has Not Made The Factual Finding That Would Trigger Obligations Under Section 6</i>	27

TABLE OF CONTENTS

2.	<i>Appellants Cannot Rely On EPA’s Prior TSCA Section 5 Order To Satisfy Section 6’s Requirements</i>	29
3.	<i>In Any Event, EPA Mooted Any Obligation Under Section 6 With Its September 2024 Federal Register Notice</i>	33
B.	There Is No Pending Mandatory Duty Under TSCA Section 7	34
	CONCLUSION	39
	CERTIFICATE OF COMPLIANCE	
	CERTIFICATE OF SERVICE	

TABLE OF AUTHORITIES

Page(s)

CASES:

<i>Air All. Hou. v. U.S. Chem. & Safety Hazard Investigation Bd.</i> , 365 F. Supp. 3d 118 (D.D.C. 2019).....	16, 21
<i>American Farm Bureau Fed’n v. EPA</i> , 559 F.3d 512 (D.C. Cir. 2009).....	30
<i>American Legal Foundation v. FCC</i> , 808 F.2d 84 (D.C. Cir. 1987).....	18, 22
<i>Center for Env’t Health v. Inhance Techs.</i> , No. CV 22-3819 (JEB), 2023 WL 2808710 (D.D.C. Apr. 6, 2023)	8
<i>Center for Env’t Health v. Regan</i> , 103 F.4th 1027 (4th Cir. 2024)	33
<i>Center for L. and Educ. v. Department of Educ.</i> , 396 F.3d 1152 (D.C. Cir. 2005).....	24
<i>Citizens for Resp. & Ethics in Wash. v. FEC</i> , 892 F.3d 434 (D.C. Cir. 2018).....	34, 37
<i>Environmental Protection Information Center v. Pacific Lumber Co.</i> , 469 F. Supp. 2d 803 (N.D. Cal. 2007).....	21
<i>Flyers Rts. Educ. Fund, Inc. v. Department of Treasury</i> , 957 F.3d 1359 (D.C. Cir. 2020).....	17, 20
<i>Friends of the Earth v. EPA</i> , 934 F. Supp. 2d 40 (D.D.C. 2013).....	37
<i>Fund Democracy, LLC v. SEC</i> , 278 F.3d 21 (D.C. Cir. 2002).....	16
<i>Gettman v. DEA</i> , 290 F.3d 430 (D.C. Cir. 2002).....	18, 20
<i>Hunt v. Washington State Apple Advert. Comm’n</i> , 432 U.S. 333 (1977).....	16, 17

TABLE OF AUTHORITIES–CONTINUED

	<u>Page(s)</u>
<i>Inhance Techs. LLC v. EPA</i> , 96 F.4th 888 (5th Cir. 2024)	4, 6, 29
<i>Lindeen v. SEC</i> , 825 F.3d 646 (D.C. Cir. 2016)	36
<i>Lujan v. Defenders of Wildlife</i> , 504 U.S. 555 (1992)	22
<i>Kloeckner v. Solis</i> , 568 U.S. 41 (2012)	36
<i>Natural Res. Def. Council v. EPA</i> , 464 F.3d 1 (D.C. Cir. 2006)	24
<i>Natural Res. Def. Council, Inc. v. Thomas</i> , 689 F. Supp. 246 (S.D.N.Y. 1988)	38
<i>Physicians Comm. for Responsible Med. v. Johnson</i> , 436 F.3d 326 (2d Cir. 2006)	38
<i>Prairie Rivers Network v. Dynegy Midwest Generation, LLC</i> , 2 F.4th 1002 (7th Cir. 2021)	24
<i>Public Citizen, Inc. v. National Highway Traffic Safety Admin.</i> , 489 F.3d 1279 (D.C. Cir. 2005)	24, 25
<i>Public Citizen, Inc. v. Trump</i> , 297 F. Supp. 3d 6 (D.D.C. 2018)	24
<i>Sierra Club v. EPA</i> , 754 F.3d 995 (D.C. Cir. 2014)	25
<i>Sierra Club v. Thomas</i> , 828 F.2d 783 (D.C. Cir. 1987)	27, 34, 35
<i>Sierra Club v. Wheeler</i> , 956 F.3d 612 (D.C. Cir. 2020)	38
<i>Sinclair Wyo. Refin. Co. LLC v. EPA</i> , 101 F.4th 871 (D.C. Cir. 2024)	28

TABLE OF AUTHORITIES–CONTINUED

	<u>Page(s)</u>
<i>Smith v. Pacific Properties and Development Corp.</i> , 358 F.3d 1097 (9th Cir. 2004)	21
<i>Sorenson Commc'ns, LLC v. FCC</i> , 897 F.3d 214 (D.C. Cir. 2018)	18, 19
<i>Students for Fair Admissions, Inc. v. Presidents & Fellows of Harvard Coll.</i> , 600 U.S. 181 (2023)	17, 20-22
<i>Summer v. Earth Island Inst.</i> , 555 U.S. 488 (2009)	22, 23
<i>TransUnion LLC v. Ramirez</i> , 594 U.S. 413 (2021)	16
<i>Viasat, Inc. v. FCC</i> , 47 F.4th 769 (D.C. Cir. 2022)	19, 20
<i>Zook v. EPA</i> , 611 F. App'x 725 (D.C. Cir. 2015)	37
 STATUTES:	
15 U.S.C. § 2601(b)(2)	3
15 U.S.C. § 2603(f)	3, 11, 14, 27, 28, 35
15 U.S.C. § 2603(f)(2)	33, 35
15 U.S.C. § 2604(a)(1)(A)	3, 4, 30
15 U.S.C. § 2604(a)(1)(B)	4
15 U.S.C. § 2604(a)(2)	3
15 U.S.C. § 2604(a)(3)	31
15 U.S.C. § 2604(a)(3)(C)	4
15 U.S.C. § 2604(e)	4, 32
15 U.S.C. § 2604(f)	4, 32

TABLE OF AUTHORITIES–CONTINUED

	<u>Page(s)</u>
15 U.S.C. § 2604(f)(2)	32
15 U.S.C. § 2604(g)	4
15 U.S.C. § 2605	36
15 U.S.C. § 2605(a)	4, 5, 15, 32
15 U.S.C. § 2605(b)(4).....	28
15 U.S.C. § 2605(b)(4)(F).....	5
15 U.S.C. § 2605(c)(2).....	28, 32
15 U.S.C. § 2605(c)(2)(A)(iii)	6
15 U.S.C. § 2605(c)(2)(A)(iv)	6
15 U.S.C. § 2605(c)(2)(B)	6
15 U.S.C. § 2605(c)(2)(C)	6
15 U.S.C. § 2605(d)	32
15 U.S.C. § 2605(d)(3)(A)(i)	36
15 U.S.C. § 2606(a)	6, 37
15 U.S.C. § 2606(a)(1).....	6, 34, 36
15 U.S.C. § 2606(a)(2).....	6, 15, 34, 36
15 U.S.C. § 2606(b)	6
15 U.S.C. § 2606(f).....	6, 34, 37
15 U.S.C. § 2619(a)(2).....	7, 14, 26, 38
REGULATIONS:	
40 C.F.R. § 702.31 <i>et seq.</i>	5
40 C.F.R. § 702.33	31

TABLE OF AUTHORITIES–CONTINUED

	<u>Page(s)</u>
40 C.F.R. § 702.37(a)(4)	31
40 C.F.R. § 702.39	30
40 C.F.R. § 702.41	31
40 C.F.R. § 702.43	30
67 Fed. Reg. 68,242 (Nov. 8, 2002).....	7
89 Fed. Reg. 37,028 (May 3, 2024)	5, 28, 31
Certain Per- and Polyfluoroalkyl Substances (PFAS) Risk Management Under the Toxic Substances Control Act (TSCA); Request for Comment, 89 Fed. Reg. 79,581 (Sept. 30, 2024)	11, 32
 LEGISLATIVE MATERIAL:	
H.R. Rep. No. 94-1679	36
 EXECUTIVE MATERIAL:	
EPA, Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA) EPA-HQ-OPPT-2023-0496: EPA Response to Comments, https://www.regulations.gov/document/EPA-HQ-OPPT-2023- 0496-0431 (last accessed Aug. 29, 2025)	5
 OTHER AUTHORITY:	
<i>Initiate</i> , Webster’s Third New International Dictionary (1976)	33

GLOSSARY

CEH	Center for Environmental Health
EPA	Environmental Protection Agency
PEER	Public Employees for Environmental Accountability
PFAS	Per- and Polyfluoroalkyl Substances
PFOA	Perfluorooctanoic Acid
TSCA	Toxic Substances Control Act

INTRODUCTION

This case did not fall out of the sky; it is the latest salvo in a long-running campaign waged by two non-governmental organizations to put Inhance Technologies LLC out of business. Inhance “fluorinates” plastic containers—which keeps volatile or dangerous substances inside and the outside environment out. Recently, both Inhance and EPA discovered that the fluorination process can unintentionally create extremely small amounts of long-chain per- and polyfluoroalkyl substances, or PFAS, as impurities in the fluorinated containers. Armed with this new information, Inhance invested in ways to reduce the amount of PFAS unintentionally created during the fluorination process.

That was not good enough for Appellants, who have filed or intervened in four separate lawsuits since December 2022 against either Inhance or EPA (or both) aiming to shut down Inhance’s business under the Toxic Substances Control Act (TSCA). All of the other lawsuits have either been dismissed or resolved in Inhance’s favor.

This lawsuit—like all of those that preceded it—is meritless. First, Appellants lack standing to pursue their claims. Appellants allege associational standing, but they lack members to supply the requisite harm. Even if Appellants could clear that hurdle, they have also failed to identify any specific person meeting all three elements of Article III standing. On the merits, Appellants base their claims on

allegations that EPA has not fulfilled a nondiscretionary duty under Sections 6 and 7 of TSCA, which provide EPA with a rulemaking process and civil cause of action, respectively, that Appellants hope will lead to a ban on Inhance's fluorination process. But the requisite agency factual findings that trigger EPA's obligations under Sections 6 and 7 have not been made. Even if that were not the case, Appellants' claims would now be moot, because EPA initiated action under Section 6 in September 2024, thus fulfilling any theoretical statutory obligation. And Appellants' Section 7 claim—asking this court to compel EPA to file a lawsuit—falls well beyond the purview of TSCA's citizen-suit provision. This Court should affirm.

ISSUES PRESENTED FOR REVIEW

1. Whether Appellants PEER and CEH have established associational standing where they lack any members and have failed to allege that any one employee of either organization can satisfy all three elements of standing.

2. Whether there is any pending nondiscretionary duty under TSCA Section 6 that EPA initiate a rulemaking where the agency has published a Federal Register notice soliciting public comment on issues related to fluorination, but not yet performed a risk evaluation or cost-benefit analysis.

3. Whether there is any pending nondiscretionary duty under TSCA Section 7 mandating that EPA file a civil action seeking immediate relief, before the agency has completed a TSCA Section 6 risk evaluation or issued a proposed rule.

PERTINENT STATUTES AND REGULATIONS

Pertinent statutes and regulations are reprinted in the Addendum.

STATEMENT OF THE CASE

A. The Toxic Substances Control Act

TSCA, as amended by the Frank R. Lautenberg Chemical Safety Act of the 21st Century, Pub. L. No. 114-182 (2016), gives EPA authority to regulate the use, manufacture, and distribution of chemical substances that present an unreasonable risk of injury to health or the environment. *See* 15 U.S.C. § 2601(b)(2). Among other things, Section 4 of TSCA instructs EPA to “initiate applicable action” under Section 5, 6, or 7 of the Act upon receipt of information “which indicates to the Administrator” that a chemical substance “presents a significant risk of serious or widespread harm to human beings.” *Id.* § 2603(f).

TSCA Sections 5 and 6 both grant EPA certain rulemaking authority, but they apply to different situations and are premised on different factual findings. Section 5 (codified at 15 U.S.C. § 2604) allows EPA to regulate a “new chemical substance” or a “significant new use” of a chemical substance. *Id.* § 2604(a)(1)(A). To use this statutory authority, EPA may issue a rule—after considering specified factors—to designate a use of a chemical substance as a significant new use. *Id.* § 2604(a)(2).

Once it does, no person may engage in the new use of that chemical substance without prior approval from EPA. *Id.* §§ 2604(a)(1)(A)–(B). EPA will approve a new use if it finds it “is not likely to present an unreasonable risk of injury to health or the environment, *without consideration of costs or other nonrisk factors.*” *Id.* §§ 2604(a)(3)(C), (g) (emphasis added). Otherwise, EPA takes action—such as imposing restrictions on the manner of use or potential exposure—“to the extent necessary to protect against such risk.” *Id.* §§ 2604(e), (f). Section 5 reflects Congress’s interest in granting EPA power “to regulate covered substances prior to their initial manufacture,” but does not apply to longstanding uses such as Inhance’s “forty-year-old fluorination process.” *Inhance Techs. LLC v. EPA*, 96 F.4th 888, 892-894 (5th Cir. 2024).

Congress built into TSCA a different rulemaking pathway for chemical substances and uses that are not “new.” Section 6 (codified at 15 U.S.C. § 2605) permits a proposed rulemaking if the Administrator determines that use of an existing chemical substance presents an “unreasonable risk of injury to health or the environment.” 15 U.S.C. § 2605(a). “By law, the Agency begins the process of determining appropriate risk management actions under TSCA section 6(a) only after a determination of unreasonable risk is made in the risk evaluation.” 89 Fed.

Reg. 37,028 (May 3, 2024).¹

Risk evaluations under Section 6 must be conducted consistent with the requirements specified in Section 6(b)(4)(F). They therefore must address a number of factors beyond what the agency considers in Sections 4(f) or 5, including: (1) the hazards and exposures for the conditions of use, including evaluation of potentially exposed or susceptible subpopulations; (2) aggregate or sentinel exposures; (3) the likely duration, intensity, and frequency of exposures under the conditions of use; and (4) the weight of the scientific evidence for any identified hazard and exposure. *Id.* § 2605(b)(4)(F); *see also* 40 C.F.R. § 702.31 *et seq.*; 89 Fed. Reg. at 37,036.

If (and only if) EPA determines through the Section 6 risk assessment that a chemical substance presents an unreasonable risk, TSCA directs the agency to promulgate a rule imposing requirements “to the extent necessary so that the chemical substance . . . no longer presents such risk.” 15 U.S.C. § 2605(a). There, too, the regulatory requirements differ: Section 6, unlike Section 5, directs EPA to conduct “a cost-benefit analysis” before commencing the rulemaking to evaluate the “economic consequences” of any prohibition or restrictions, including likely effects on the national economy, small business, and technological innovation. 15 U.S.C.

¹ EPA, Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA) EPA-HQ-OPPT-2023-0496: EPA Response to Comments, at § 1.2, <https://www.regulations.gov/document/EPA-HQ-OPPT-2023-0496-0431> (last accessed Aug. 29, 2025).

§ 2605(c)(2)(A)(iii), (iv). EPA also must consider “technically and economically feasible alternatives” when “selecting among prohibitions and other restrictions.” 15 U.S.C. §§ 2605(c)(2)(B), (C).

It makes sense that Section 6 requires more robust agency analysis before regulatory obligations kick in, because this portion of TSCA addresses chemical substances that are already used in commerce. Agency action under Section 6 thus implicates substantial industry reliance interests. *Inhance*, 96 F.4th at 894 (explaining that “Congress intended for the EPA to consider more carefully the effects of its regulations on manufacturing processes that have previously existed”).

Section 7 provides the agency with a completely different recourse: an enforcement action in court to address certain “imminent hazards.” *Id.* § 2606(a). If EPA determines that a chemical presents an “imminent and unreasonable risk of serious or widespread injury” it may commence a civil action for relief, including seizure of the chemical or an order halting its production. *Id.* §§ 2606(a)(1), (b), (f). EPA generally has discretion to bring such an action. The only non-discretionary grant of authority in Section 7 is triggered where (1) EPA has conducted a risk assessment under Section 6 *and* decided to proceed with a rulemaking, and (2) in doing so, concludes that the chemical is “imminently hazardous” but has not made the Section 6 rule immediately effective upon publication. *Id.* §§ 2606(a)(2), (f).

All of these statutory provisions are overseen and implemented by EPA. TSCA gives members of the public only a few narrow avenues to request that EPA take regulatory action. Section 21, for example, authorizes citizens to petition EPA to “initiate a proceeding” for issuing a rule or order under Sections 4, 5, 6, or 8 of the Act. And Section 20—the citizen-suit provision relied upon by Appellants here—allows members of the public a limited right to bring an action to compel EPA “to perform any act or duty under [TSCA] which is *not discretionary*.” 15 U.S.C. § 2619(a)(2) (emphasis added). That’s the extent of private party involvement.

B. Inhance’s Fluorination Process

Inhance fluorinates plastic containers using elemental fluorine. Fluorination imparts barrier properties to the plastic container, keeping volatile or dangerous substances from leaching out of the container. Inhance has been fluorinating containers for decades. EPA has long recognized the benefits conferred by fluorination, issuing standards requiring the control of evaporative emissions by permeation from polyethylene fuel tanks through processes like Inhance’s fluorination. 67 Fed. Reg. 68,242, 68,289 (Nov. 8, 2002).

Recently, Inhance and EPA discovered that the fluorination process can unintentionally create extremely small amounts of PFAS as an impurity in the fluorinated container. JA195. EPA’s enforcement office issued a Notice of Violation to Inhance in March 2022, asserting that the company’s decades-old

fluorination process violated TSCA Section 5 because Inhance was engaged in a “significant new use” of long-chain PFAS without seeking prior approval. JA22.

C. Litigation Over Inhance’s Fluorination Process Ensues

The Federal Government and Appellants each filed enforcement actions against Inhance under TSCA Section 5. The Federal Government first filed its enforcement action in the Eastern District of Pennsylvania on December 19, 2022. *United States v. Inhance Techs. LLC*, ECF No. 1, No. 5:22-cv-05055-JFM (E.D. Pa.). Eight days later, Appellants initiated a citizen-suit under TSCA Section 20(a) in federal court in the District of Columbia. The D.C. district court dismissed Appellants’ lawsuit pursuant to TSCA’s diligent-prosecution bar. *Center for Env’t Health v. Inhance Techs.*, No. CV 22-3819 (JEB), 2023 WL 2808710, at *4 (D.D.C. Apr. 6, 2023). Appellants then intervened in the Pennsylvania lawsuit, unopposed by Inhance. *United States v. Inhance Techs. LLC*, ECF Nos. 33, 34, No. 5:22-cv-05055-JFM (E.D. Pa. Apr. 26, 2023).

In December 2023, while its enforcement case was pending, EPA issued two unilateral orders under TSCA Section 5, directing Inhance to cease all manufacturing or processing of long-chain PFAS, with the effect of mandating a total shutdown of Inhance’s fluorination operations. JA53. Inhance filed a petition for review of these orders in the Fifth Circuit, accompanied by an unopposed motion for expedited

briefing and stay pending appeal due to the existential threat to the company. *Inhance*, 96 F4th at 890.

The Fifth Circuit held EPA had exceeded its statutory authority under TSCA Section 5 and vacated both orders. *Id.* at 896. Specifically, the court noted that Inhance’s fluorination process was not “new,” and thus that EPA had no authority to regulate it under Section 5. *Id.* at 894. The court also noted the more robust protections that would have been available to regulated entities had the agency instead taken action under Section 6. *Id.* (“Unlike Section 5, Section 6 requires the EPA to conduct a cost-benefit analysis, weighing the negative effects of the chemical substance against the benefits of the substance as well as the economic consequences of prohibiting or limiting the substance.”).

After the Fifth Circuit’s ruling, Appellants and the Government dismissed the enforcement action pending in the Eastern District of Pennsylvania. Before acknowledging the dismissal, the district court chastised both for filing unauthorized motions and other irregularities in the litigation. *United States v. Inhance Tech. LLC*, ECF No. 103 n.1, No. 5:22-cv-05055-JFM (E.D. Pa. May 20, 2024).

Undeterred, in February 2024, Appellants filed a Freedom of Information Act case against EPA. *Public Emps. for Env’t Responsibility v. EPA*, No. 1:24-cv-00445-JEB (D.D.C. Feb. 15, 2024). In that case, Appellants seek disclosure of highly sensitive confidential research and development information that Inhance

submitted to EPA voluntarily as well as in response to information requests. Inhance intervened in that suit and has separately challenged EPA’s decision to release certain confidential business information, and the dispute continues to play out in district court.

In April 2024, Appellants petitioned EPA to promulgate regulations under Section 6 of TSCA addressing the fluorination of plastic containers. JA47–64. A month later, Appellants filed a notice of intent to file suit against EPA—before the agency had even had the chance to consider their petition. JA17. EPA granted the petition in July 2024, JA38–42, informing Appellants that the agency would “promptly commence an appropriate proceeding under TSCA Section 6.” JA40.

Five days later, Appellants filed this suit anyway, seeking to compel EPA to take action against Inhance under Sections 6 and 7 of TSCA. JA8–37. Among other things, Appellants sought an order compelling EPA to “immediately propos[e] a rule under TSCA section 6(a) prohibiting the production of PFOA during the Inhance fluorination process” as well as an order requiring EPA to “immediately file an imminent hazard action under TSCA section 7 against Inhance to prohibit the formation of PFOA during the fluorination process”—or, alternatively, “make its proposed rule under section 6(a) imposing such a ban immediately effective upon publication in the Federal Register.” JA33, 35. Inhance promptly moved to intervene.

D. EPA’s Initiation Of Section 6 Procedures

In September 2024, EPA published a notice in the Federal Register seeking information “with respect to regulation of ... PFAS formed during the fluorination of plastic containers.” Certain Per- and Polyfluoroalkyl Substances (PFAS) Risk Management Under the Toxic Substances Control Act (TSCA); Request for Comment, 89 Fed. Reg. 79,581, 79,582 (Sept. 30, 2024); JA44. In the notice, EPA stated that it had “identified information necessary to inform the Agency’s path forward,” which included “information regarding the number, location, and uses of fluorinated containers,” any uses that were “critical to the national economy, national security, or critical infrastructure,” any “alternatives to the fluorination process,” and “measures to address risk” from PFAS impurities. JA44.

EPA then moved to dismiss Appellants’ complaint, explaining that the agency’s September 30, 2024 notice fulfilled any statutory obligation EPA may have had. EPA pointed out that TSCA requires only that EPA “initiate applicable action” under Sections 5, 6, *or* 7 when the triggering determination is made—it does not require that the agency proceed to rulemaking. 15 U.S.C. § 2603(f).

E. The District Court Dismisses The Lawsuit

In December 2024, the District Court granted the Government’s motion to dismiss. It reasoned that EPA’s notice seeking the information required in a Section 6 rulemaking “rendered moot Plaintiffs’ first claim for relief.” JA202. As for

Appellants' Section 7 claim, the court concluded that it fell beyond the purview of TSCA's citizen-suit provision. JA205. Having ruled the complaint should be dismissed, the court denied Inhance's motion to intervene as moot. JA205.

Appellants timely appealed the District Court's ruling, JA206-207, and Inhance timely appealed the District Court's denial of intervention. JA208. Inhance also moved to intervene in the merits appeal brought by Appellants the same day. This Court granted Inhance's motion to intervene in the merits appeal on April 22, 2025, and dismissed Inhance's separate appeal of the District Court's denial of its request to intervene.

SUMMARY OF ARGUMENT

This litigation faces multiple justiciability problems, and the Court can affirm based on any of them. As a threshold matter, Appellants lack standing. Appellants' claims also fail because EPA has not made the factual findings that would trigger a non-discretionary duty to act under Sections 6 and 7. And the District Court correctly held that Appellants' Section 6 argument was mooted by EPA's September 2024 action, and that it lacked subject matter jurisdiction over their Section 7 claim.

I. Appellants' arguments have an insurmountable threshold Article III problem: PEER and CEH lack standing to raise a challenge concerning EPA's duties under Section 6 and 7. On appeal, they attempt to invoke associational standing, but as non-membership organizations, Appellants cannot represent the interests of

members they do not have. Their effort to avoid this basic defect by recasting their staff and supporters as effective members is contrary to law. Whether a non-membership organization has an effective membership turns on specific considerations—such as whether those asserted to act effectively as members finance the organization, guide its activities, or select its membership—that Appellants do not show are satisfied here. Appellants have offered only conclusory and general assertions that their staff and supporters meet those criteria. That does not suffice under the Supreme Court’s or this Court’s precedent.

But even if it did, Appellants must also identify at least one putative member that has standing in her own right. They did not even attempt to do so below, and their belated effort to do so now turns on affidavits filed for the first time on appeal. Because those affidavits were never before the District Court, they are not properly before this Court either. And they are insufficient regardless. They do not demonstrate the requisite *substantially* increased risk of harm to affiants absent a Section 6 rulemaking or a Section 7 imminent hazard lawsuit because, by Appellants’ own telling, their environment is so inundated with PFAS-containing materials that even if EPA ordered Inhance to stop its operations, those affiants would still be exposed to pervasive levels of PFOA.

II. Appellants’ claims fail for substantive reasons as well. The citizen-suit provision on which Appellants rely creates a private right of action to compel EPA

to fulfill a nondiscretionary duty. *See* 15 U.S.C. § 2619(a)(2). But Appellants have not identified any unfulfilled nondiscretionary duties.

A. Appellants point first to EPA’s Section 4(f) obligation to “initiate applicable action” under one of three provisions when it is in receipt of information “which indicates to the Administrator that there may be a reasonable basis to conclude that a chemical substance or mixture presents a significant risk of serious or widespread harm to human beings.” 15 U.S.C. § 2603(f). Appellants assert that EPA had enough information in its possession to have drawn that conclusion. But the statute gives discretion to the agency—not a third party, and not this Court—to determine whether there is a reasonable basis to conclude that a chemical substance meets the “significant risk of serious harm” requirement.

Appellants’ contention that EPA’s prior Section 5 orders require it to skip that step is wrong on several grounds. Those orders were vacated by the Fifth Circuit, were based on now stale data, and resulted from a process starkly different from the risk evaluation and rulemaking analysis mandated for a Section 6 proceeding. Moreover, TSCA does not permit EPA to issue rules that will disrupt existing enterprises or integrated markets—like Inhance’s fluorination process—without (1) completing a draft risk evaluation and undertaking a cost-benefit analysis, (2) running that draft evaluation through public comment, (3) publishing a final risk evaluation, and then (4) fully analyzing all intended and unintended consequences

of various risk-mitigation strategies. The Section 5 process is far less exacting because only new uses are at stake. Appellants’ conflation of those requirements contravenes Congress’s carefully crafted statutory scheme. The District Court correctly refused to take that step.

B. Even assuming away all of these problems, the District Court correctly concluded that EPA *did* “initiate applicable action” under one of the three proceedings cross-referenced in Section 4(f) when it commenced the information-gathering process under Section 6 in September 2024. As the Government persuasively argues, that moots Appellants’ claims.

C. Appellants have likewise failed to identify a mandatory duty under Section 7. For the most part, EPA’s powers under Section 7 are discretionary. The only arguably mandatory power in Section 7 kicks in only if EPA has [1] completed a Section 6 risk assessment; [2] determined to proceed with a Section 6 rulemaking; [3] found an imminent hazard; and [4] nonetheless decided not to make the Section 6 rule immediately effective. 15 U.S.C. § 2606(a)(2), § 2605(a). None of those things has happened here.

ARGUMENT

I. PEER AND CEH LACK STANDING.

Article III of the Constitution limits the jurisdiction of federal courts to “Cases” and “Controversies.” This requirement limits the role of the Federal

Judiciary in our system of separated powers. For a plaintiff to get in the federal courthouse door and obtain judicial relief, the plaintiff must have a “personal stake” in the dispute. *TransUnion LLC v. Ramirez*, 594 U.S. 413, 423 (2021).

Appellants claim a personal stake based on the interests of their staff and supporters, invoking the associational standing doctrine. Opening Br. 27. But associational standing is wholly inapt here. To qualify, an organization must show that: “(a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization’s purpose; and (c) neither the claim asserted nor the relief requested requires the participation in the lawsuit of each of the individual members.” *Hunt v. Washington State Apple Advert. Comm’n*, 432 U.S. 333, 343 (1977)).

Appellants stumble at the first step because (A) Appellants’ staff and supporters are not members of their organizations in the relevant sense and (B) Appellants’ staff and supporters do not have standing in their own right. *See Fund Democracy, LLC v. SEC*, 278 F.3d 21, 25 (D.C. Cir. 2002) (denying associational standing on this basis).

A. Appellants Are Not Membership Organizations And Therefore Do Not Qualify For Associational Standing.

“Implicit” in the associational standing test “is that the organization in question has members.” *Air All. Hou. v. U.S. Chem. & Safety Hazard Investigation Bd.*, 365 F. Supp. 3d 118, 128 (D.D.C. 2019). But Appellants do not. They are

concededly “not traditional membership organizations.” Opening Br. 28. Appellants try to overcome this failure by citing a line of decisions extending associational standing to certain entities lacking a formal membership that nevertheless have been permitted to represent individuals who are “*effectively* members.” *Students for Fair Admissions, Inc. v. Presidents & Fellows of Harvard Coll.*, 600 U.S. 181, 200 (2023) (“*SFFA*”). But Appellants’ staff and supporters do not qualify for effective-member status.

In the seminal case of *Hunt v. Washington*, the Supreme Court permitted the Washington State Apple Advertising Commission to represent the interests of non-member apple growers and dealers because the growers and dealers possessed “all of the indicia of membership.” 432 U.S. at 344. They “alone elect[ed] the members of the Commission,” “alone . . . serve[d] on the Commission,” and “alone finance[d] its activities.” *Id.*

Following *Hunt*’s “indicia of membership” test, this Court has looked to whether putative members “play a role in selecting the organization’s leadership, in guiding the organization’s activities, and in financing the organization’s activities.” *Flyers Rts. Educ. Fund, Inc. v. Department of Treasury*, 957 F.3d 1359, 1361 (D.C. Cir. 2020). In *Flyers Rights*, for example, the Court applied these criteria to hold that a non-profit organization specializing in “educating airline passengers of their rights and advocating on their behalf,” *id.* at 1360, was entitled to assert associational

standing because the non-member airline passengers it claimed to represent “guide[d] the organization’s activity” and were responsible for a majority of its funding, *id.* at 1362.

But this Court has repeatedly declined to recognize associational standing when *Hunt*’s indicia of membership are unmet. In *American Legal Foundation v. FCC*, the Court held that media consumers were not effective members of a media watchdog group because there was no record evidence that this constituency “play[ed] any role in selecting [the organization’s] leadership, guid[ed] [its] activities, or finance[ed] those activities.” 808 F.2d 84, 90 (D.C. Cir. 1987). The Court thus could not “conclude, as could the *Hunt* Court, that the organization [was] the functional equivalent of a traditional membership organization.” *Id.*

Similarly, in *Gettman v. DEA*, this Court rejected a pro-cannabis magazine’s argument that it had associational standing to represent the interests of its readers. 290 F.3d 430, 435 (D.C. Cir. 2002). The Court explained that “readership is not the same as membership.” *Id.* And the magazine had not shown that its members “played any role in selecting its leadership, guiding its activities, or financing those activities.” *Id.*

This Court has also denied associational standing when an organization fails to address “the ‘indicia of a traditional membership’ association” altogether. *Sorenson Commc’ns, LLC v. FCC*, 897 F.3d 214, 225 (D.C. Cir. 2018). The plaintiff

entity in *Sorenson* attempted to cast “passive subscribers to its e-mail list and individuals who ‘follow’ the group’s Facebook page” as members. *Id.* But it failed to explain how those putative members funded or controlled the organization. *Id.* The Court therefore declined to credit the entity’s “conclusory and general assertions” of being a membership organization. *Id.*

In *Viasat, Inc. v. FCC*, a group seeking associational standing provided “no insight into how it relates with its members.” 47 F.4th 769, 781 (D.C. Cir. 2022). The group submitted affidavits of putative members, but those affidavits failed to “describe[] involvement in the Group beyond a bare assertion of membership.” *Id.* at 782. “And the Group’s own affidavit, submitted by its operating officer, ma[de] no reference to membership.” *Id.* The Court was thus “left with no basis to determine whether the requisite elements of standing have been met.” *Id.*

Appellants have likewise failed to meet their burden to demonstrate that their staff and supporters satisfy *Hunt*’s criteria for effective membership here.

With respect to supporters, Appellants offered “only conclusory and general assertions.” *Sorenson*, 897 F.3d at 225. Nothing in the Opening Brief speaks to whether supporters “finance the organization, guide its activities, or select its membership.” *Viasat, Inc.*, 47 F.4th at 781. Appellants simply make the “bare assertion,” *id.* at 782, that their supporters “have ‘a sufficient amount of interaction to influence the organization’s activities,’ ” Opening Br. 28 (quoting *Flyers Rights*,

957 F.3d at 1362). Because Appellants have “given us no insight into how it relates with its [supporters],” they have not met their burden to demonstrate that their supporter are effective members under *Hunt*. *Viasat, Inc.*, 47 F.4th at 781.

Appellants offer only slightly more with respect to their staff, stating that two individuals—Dr. Bennett and Mr. Fox—“exercise considerable [i]nfluence over their organization’s scientific and advocacy work.” Opening Br. 29. Appellants state that Dr. Bennett and Mr. Fox are “senior employees.” *Id.* at 27. Dr. Bennett is PEER’s Science Director, and Mr. Fox is CEH’s Senior Legislative Counsel. *Id.* But even if that were enough to demonstrate that Dr. Bennett and Mr. Fox “guide [PEER’s and CEH’s] activities,” that would only check one of *Hunt*’s three boxes. *Viasat, Inc.*, 47 F.4th at 781. Appellants make no claim that Dr. Bennett or Mr. Fox “finance the organization[s]” or “select [their] membership.” *Id.*

More fundamentally, Dr. Bennett and Mr. Fox are clearly not “*effectively* members” of their respective organizations. *SFFA*, 600 U.S. at 200. Just as “readership is not the same as membership,” *Gettman*, 290 F.3d at 435, being an employee of an organization is not the same as being a member of that organization. Appellants have not identified a single case in which a court has recognized associational standing based solely on the interests of its staff.

Appellants appear to cite *Air Alliance* for the proposition that an organization satisfies *Hunt* when “Board members and the Executive Director exercise a

governance function in the organization.” Opening Br. 28 (citing *Air Alliance*, 365 F. Supp. at 129). But that would be true of any organization, rendering the membership requirement a nullity. *Air Alliance* does not support the rule Appellants suggest. The membership organization at issue there was “a traditional membership organization for standing purposes,” which meant that “the court need not consider the *Hunt* factors.” *Air Alliance*, 365 F. Supp 3d at 129; *see also SFFA*, 600 U.S. at 201 (noting that when “an organization has identified members and represents them in good faith, our cases do not require further scrutiny into how the organization operates”).

Appellants’ invocation of *Smith v. Pacific Properties and Development Corp.*, 358 F.3d 1097 (9th Cir. 2004) and *Environmental Protection Information Center v. Pacific Lumber Co.*, 469 F. Supp. 2d 803 (N.D. Cal. 2007), is even further afield. There was no question that the organizational plaintiffs in *Smith* and *Pacific Lumber* were membership organizations—the only question was whether their members had standing in their own right. *See Smith*, 358 F.3d at 1102 (“The district court determined that DRAC lacked representational standing because it could not demonstrate that any one of its members, including the tester Smith, had standing to sue”); *Pacific Lumber*, 469 F. Supp. at 814 (“In its motion for summary judgment, PALCO asserts only that EPIC has failed to show that any of its members would have standing on their own behalf”).

Appellants have done no more than “locate[] certain individuals who agree with [their] complaint.” *American Legal Foundation*, 808 F.2d at 91. That is not enough to demonstrate that they are “the functional equivalent of a traditional membership organization.” *Id.* at 90. Associational standing is therefore unavailable to Appellants, even under the *Hunt* exception.

B. Appellants’ Staff And Supporters Do Not Have Standing In Their Own Right.

Even if Appellants could be deemed “genuine membership organization[s] in substance” under *Hunt*, they would still lack associational standing because Appellants have not demonstrated that any of their putative members “would otherwise have standing to sue in their own right.” *SFFA*, 600 U.S. at 199. Associational standing “require[s] plaintiff-organizations to make specific allegations establishing that at least one identified member had suffered or would suffer harm.” *Summer v. Earth Island Inst.*, 555 U.S. 488, 497-498 (2009). An individual has Article III standing to sue when she can show: (1) she has suffered an “injury in fact” that is concrete and particularized, and actual or imminent rather than conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-561 (1992).

Appellants failed below to make any specific allegations identifying any putative member that has or would suffer harm in the absence of a Section 6 rulemaking or Section 7 imminent hazard action. They merely alleged that some unidentified number of their staff and supporters “may” (or may not) come into contact with fluorinated containers that *may* (or may not) contain PFAS. JA13-14.

That does not suffice, for many reasons. *First*, the Supreme Court has squarely rejected “probabilistic standing” in favor of “requiring plaintiff-organizations to make specific allegations establishing that at least one identified member had suffered or would suffer harm.” *Summers*, 555 U.S. at 498. Appellants’ failure to connect their alleged injury-in-fact to a specific putative member renders their standing theory a nonstarter.

Perhaps recognizing that shortfall in their pleadings, Appellants attempt to backfill the record with the affidavits of Dr. Bennett and Mr. Fox, which Appellants present now for the first time on appeal. Opening Br. 29-30. These submissions are not properly before the Court. *See e.g., Summers*, 555 U.S. at 495 n.* (“After the District Court had entered judgment, and after the Government had filed its notice of appeal, respondents submitted additional affidavits to the District Court. We do not consider these.”). As the Supreme Court explained when faced with similar tardy standing submissions, “[i]f the [environmental organizations] had not met the challenge to their standing at the time of judgment, they could not remedy the defect

retroactively.” *Id.*; accord *Prairie Rivers Network v. Dynegy Midwest Generation, LLC*, 2 F.4th 1002, 1011-12 (7th Cir. 2021). The same is true here. The Court should limit its review to the record that was before the District Court, which did not include these new affidavits.

Second, even aside from Appellants’ failure to identify an individual member that has been—or likely will be—harmed, the alleged harm itself is insufficient. The mere *risk of possible* exposure to PFOA or other PFAS is not enough to establish a concrete and particularized injury. *See Natural Res. Def. Council v. EPA*, 464 F.3d 1, 6 (D.C. Cir. 2006) (“Were all purely speculative ‘increased risks’ deemed injurious, the entire requirement of ‘actual or imminent injury’ would be rendered moot, because all hypothesized, nonimminent ‘injuries’ could be dressed up as ‘increased risk of future injury.’”) (quoting *Center for L. and Educ. v. Department of Educ.*, 396 F.3d 1152, 1161 (D.C. Cir. 2005)). The D.C. Circuit requires that a plaintiff show “both (i) a *substantially* increased risk of harm and (ii) a *substantial* probability of harm with that increase taken into account.” *Public Citizen, Inc. v. National Highway Traffic Safety Admin.*, 489 F.3d 1279, 1295 (D.C. Cir. 2005). That “standard is not easily met.” *Public Citizen, Inc. v. Trump*, 297 F. Supp. 3d 6, 21-22 (D.D.C. 2018). Appellants have shown neither. But this Court has made clear that “the increased risk must be nontrivial, . . . and sufficient to take a suit out of the

category of the hypothetical.” *Sierra Club v. EPA*, 754 F.3d 995, 1001 (D.C. Cir. 2014) (internal quotation marks omitted).

Appellants’ allegations that their supporters “use a variety of products packaged in plastic containers that *may* be fluorinated, JA13-14 (emphasis added), does not suffice. Far from alleging a “substantial probability of harm,” *Public Citizen*, 489 F.3d at 1295, Appellants admit that they “cannot ascertain whether” the products their putative members come into contact with were fluorinated and/or “contain PFOA and other PFAS.” JA13-14.

Even if admissible, Appellants’ late-breaking affidavits likewise fail to demonstrate a “*substantially* increased risk of harm.” *Public Citizen*, 489 F.3d at 1295. Appellants do not even know if the containers they come into contact with were fluorinated. Instead, they allege only that the containers “are within product classes” that Inhance has fluorinated in the past. ADD-9 ¶ 16. Moreover, by Appellants’ own telling, the environment is so inundated with PFAS-containing materials that they cannot be avoided. *See e.g.*, ADD-37 ¶ 33. Dr. Bennett and Mr. Fox would continue to be exposed to these materials even if fluorinated containers were banned by EPA. Any container—fluorinated or not—could contain PFOA due to materials used in manufacturing of the container (*i.e.*, prior to whether or not the container was fluorinated), or due to PFOA introduced by the product stored within the container.

Third, and relatedly, Appellants have not identified any theoretical injury that may be “fairly traceable” to EPA’s decision not to engage in a TSCA Section 6 rulemaking or Section 7 imminent hazard action or redressed by their requested relief of an injunction requiring initiation of a Section 6 rulemaking or Section 7 imminent hazard action. A Section 6 rulemaking—even if appropriate—may very well result in no action, or something less than shutting down Inhance’s fluorination process. *See supra* pp. 5-6. It is entirely speculative whether any plastic containers that “may” have been fluorinated by Inhance and “may” contain PFAS would contain sufficient levels of PFAS to be covered by a rulemaking that may or may not take place.

Even assuming—and it is assuming a great deal—that Appellants’ requested relief resulted in EPA ordering a halt to the fluorination of all containers (and their importation), that is still unlikely to meaningfully reduce the exposure of Appellants’ putative members to PFOA and other PFAS.

II. EPA IS NOT IN VIOLATION OF A NONDISCRETIONARY DUTY.

Standing issues aside, the District Court’s ruling was correct and should be affirmed. There is no basis for a court to order further regulatory action under either TSCA Section 6 or Section 7.

The citizen-suit provision authorizes Appellants to compel EPA to fulfill an “act or duty” which is “not discretionary.” 15 U.S.C. § 2619(a)(2). A

nondiscretionary duty “ ‘categorically mandate[s]’ that all specified action be taken by a date-certain deadline.” *Sierra Club v. Thomas*, 828 F.2d 783, 791 (D.C. Cir. 1987) *other holdings superseded by statute as stated in Mexichem Specialty Resins, Inc. v. EPA*, 787 F.3d 544, 553 n.6 (D.C. Cir. 2015). Appellants say there are two unfulfilled nondiscretionary duties here, one under Section 6 and the other under Section 7.

Both assertions are incorrect, as the District Court correctly held.

A. There Is No Pending Mandatory Duty Under TSCA Section 6.

1. EPA Has Not Made The Factual Finding That Would Trigger Obligations Under Section 6.

Appellants’ Section 6 arguments actually start with Section 4(f). They argue that under that provision, EPA has a duty to “initiate applicable action” under Section 6 when it has information “which indicates to the Administrator that there may be a reasonable basis to conclude that a chemical substance or mixture presents a significant risk of serious or widespread harm to human beings.” 15 U.S.C. § 2603(f). Appellants argue that EPA had sufficient information to conclude that such a risk existed here. Opening Br. 33-47.

Appellants’ argument falters from the get-go because the relief they seek—immediate publication of a proposed rule under Section 6—trips over multiple layers of agency discretion and required procedures. Section 4(f) itself is triggered only where the available information “*indicates to the Administrator*”—not a third party,

and not a court—that a reasonable basis exists to conclude that the chemical substance presents a significant risk of serious and widespread harm. 15 U.S.C. § 2603(f) (emphasis added). The Administrator has made no such finding here. End of story.

Or not end of story, because there is more. Section 6 also does not permit—let alone require—EPA to proceed with a rulemaking until it first completes a risk assessment and cost-benefit analyses and determines that a rulemaking is warranted. Section 6(b)(4)(A) requires that EPA conduct risk evaluations “to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment.” *Id.* § 2605(b)(4). *See also* 89 Fed. Reg. 37,028. Section 6(c)(2) requires the agency to conduct cost-benefit analyses before promulgating a rule. *See* 15 U.S.C. § 2605(c)(2).

As the District Court explained, the initiation of a Section 6 rulemaking process “begin[s] with a request for information.” JA202. What happens next is up to the agency: EPA reviews the information obtained through the data gathering and risk assessment process, performs a cost-benefit analysis, and decides—based on the additional information that it has gathered—whether to issue a proposed rule. The agency has discretion to get off the train at each stop. *See, e.g., Sinclair Wyo. Refin. Co. LLC v. EPA*, 101 F.4th 871, 877 (D.C. Cir. 2024).

TSCA's citizen-suit provision is limited to compelling *non-discretionary* duties. It therefore is not an appropriate vehicle to pursue a claim that the agency abused its discretion in refusing to take each and every discretionary step in the Section 6 process and ultimately promulgate a final rule.

2. Appellants Cannot Rely On EPA's Prior TSCA Section 5 Order To Satisfy Section 6's Requirements.

Appellants argue that EPA's prior TSCA Section 5 orders, including its risk determination under Section 5(a)(3)(A), obviate the Section 6 risk evaluation and rulemaking analysis processes and trigger a mandatory duty to immediately promulgate a Section 6 rulemaking. Opening Br. 45. That is wrong several times over.

For one, the supposed predicate for further agency action no longer exists: The Fifth Circuit vacated EPA's Section 5 orders after concluding that Inhance's decades-old fluorination process could not be regulated as a "significant new use" under Section 5. *Inhance Techs. LLC*, 96 F.4th at 895. Vacated agency orders have no force or effect; by definition they cannot satisfy Section 6's risk-evaluation requirement.

What's more, EPA entered the now-vacated Section 5 orders following an administrative process based on information that existed, at the latest, in 2022. Since then, Inhance has further reduced the presence of the small amounts of PFAS inadvertently created during the fluorination process. If EPA were to ignore those

process enhancements by resurrecting a years-old analysis undertaken as part of a now-vacated Section 5 order, that action would not reflect the current risk profile of Inhance's fluorination process. It is entirely appropriate for EPA to consider current conditions before taking action (or not taking action, as the case may be). *American Farm Bureau Fed'n v. EPA*, 559 F.3d 512, 521 (D.C. Cir. 2009).

It is not just that the facts on the ground have changed. So has the legal landscape, now that the dispute is viewed through the lens of Section 6. As EPA explained, "[a] section 6 risk evaluation is a different undertaking, with different procedural and substantive requirements," than a Section 5 risk assessment. EPA Br. 32; *see also id.* at 6-7. Section 6 rulemakings apply to chemical substances already used in the marketplace; as such, EPA has a higher burden to regulate them. In contrast, a risk assessment under Section 5 is less burdensome because it applies only to a "new use." 15 U.S.C. § 2604(a)(1)(A).

When conducting a Section 6 risk evaluation, EPA regulations: (1) dictate the components of a risk evaluation that must be developed (*e.g.*, scope, hazard assessment, exposure assessment, risk characterization, risk determination), 40 C.F.R. § 702.39; (2) require the publication and solicitation of public comments on the draft risk evaluation before publication of the final risk evaluation in the Federal Register, 40 C.F.R. § 702.43; and (3) mandate the risk assessment be subject to peer

review, 40 C.F.R. § 702.41. Appellants do not claim that EPA’s analysis under Section 5 comported with the requirements applicable to a Section 6 risk evaluation.

Nor could they. EPA’s “risk assessment” under Section 5 was qualitative, not quantitative, in nature. EPA’s prior assessment did not, for example, examine other conditions of use for the relevant PFAS compounds. Section 5 merely requires EPA to determine if a new chemical or significant new use presents an unreasonable risk based on the agency’s review of *pre-manufacture* notices and significant *new use* notices it receives. *See* 15 U.S.C. § 2604(a)(3). When evaluating risk under Section 6, however, the agency must consider *all* conditions of use of a chemical substance, meaning all “circumstances . . . under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.” 40 C.F.R. § 702.33; 40 C.F.R. § 702.37(a)(4) (“EPA will not exclude conditions of use from the scope of the risk evaluation.”). In newly finalized TSCA regulations, EPA explained that evaluating all conditions of use in a Section 6 rulemaking was not only mandated by TSCA, but also necessary “from a scientific perspective to ensure development of a technically sound determination as to whether a chemical substance presents an unreasonable risk.” 89 Fed. Reg. at 37,032 (rejecting commenters’ suggestion that the agency could evaluate only “a subset of a chemical’s conditions of use”).

After a final risk determination, moreover, EPA must undertake a number of cost-benefit analyses before selecting a particular risk-mitigation measure. 15 U.S.C. § 2605(a), (c)(2), (d). As explained in EPA’s Federal Register notice, EPA needs “information about alternative fluorination processes” so that it can “consider the availability of technically and economically feasible alternatives that benefit health or the environment, as required under TSCA section 6(c)(2)(C).” 89 Fed. Reg. at 79,582. EPA also needs “input about . . . the number, location, and uses of fluorinated containers to inform [EPA’s] consideration of compliance dates” as required by “TSCA section 6(d).” *Id.* And it needs information about “uses critical to the national economy, national security, or critical infrastructure (which may include uses in medical devices)” so that it may consider “exemptions from regulation and conditions on such exemptions, as outlined in TSCA section 6(g).” *Id.*

These analyses are not part of the Section 5 process, in which EPA generally is not permitted to consider non-risk factors. 15 U.S.C. § 2604(e), (f). This Court should reject Appellants’ conflation of Sections 5 and 6. TSCA spells out distinct regulatory requirements for different pathways under the statute, and Section 5 proceedings cannot be pasted into a Section 6 rulemaking.

3. *In Any Event, EPA Mooted Any Obligation Under Section 6 With Its September 2024 Federal Register Notice.*

Even if a Section 6 duty were somehow triggered, it was fulfilled by EPA's Federal Register notice soliciting information pertinent to a Section 6 rulemaking. All that Section 4(f) requires is that EPA "initiate applicable action" by the statutory deadline. 15 U.S.C. § 2603(f)(2). To "initiate" means to begin something. *Initiate*, Webster's Third New International Dictionary (1976). EPA initiates a Section 6 process by publishing a request for information. That is all that Section 4(f) and Section 6 collectively require.

Once EPA initiated the Section 6 process, JA43, Appellants' claims—even assuming they had any merit at their inception—became moot. *Ctr. for Env't Health v. Regan*, 103 F.4th 1027, 1038 (4th Cir. 2024) (where TSCA requires EPA to "initiate a proceeding for the issuance of a rule or an order," "all the district court can provide . . . is an order directing the EPA to initiate a proceeding for a rule or order"); *id.* at 1039 ("[B]y promptly commencing a proceeding for determining how to best test PFAS, the EPA gave Petitioners all that they were entitled to receive."). "To the extent that Plaintiffs' prayer for relief asks for more, it goes beyond TSCA's limited language and thus fails to state a claim for relief." JA202. The District Court's dismissal should be affirmed.

B. There Is No Pending Mandatory Duty Under TSCA Section 7.

PEER and CEH likewise have no claim to relief under Section 7. Section 7 grants EPA general discretion to address imminent hazards in carefully defined cases. When EPA determines a chemical substance poses an imminent risk, *see* 15 U.S.C. § 2606(f), it “may” choose to “commence an action” for relief “notwithstanding the existence” of any separate rule, order, or proceeding. *Id.* § 2606(a)(1). This language is permissive, not mandatory. *Citizens for Resp. & Ethics in Wash. v. FEC*, 892 F.3d 434, 439 (D.C. Cir. 2018) (“To state the obvious, the word ‘may’ imposes no constraints on the Commission’s judgment about whether, in a particular matter, it should bring an enforcement action.”). And it imposes no time limit on EPA to act. *See Thomas*, 828 F.2d at 791 (D.C. Cir. 1987) (explaining that a “clear-cut nondiscretionary duty” exists when “*all* specified action” must “be taken by a date-certain deadline”). These kinds of discretionary decisions may not be enforced under TSCA’s citizen-suit provision.

To get around this barrier, PEER and CEH try to invoke a narrow exception not applicable here. Section 7(a)(2) provides that if EPA decides not to make a Section 6 rule “immediately effective . . . with respect to an imminently hazardous chemical substance,” it “shall” bring an action for relief. 15 U.S.C. § 2606(a)(2). This provision is triggered only by a Rube Goldberg-esque series of events: EPA must have (i) completed a Section 6 risk evaluation, (ii) commenced a Section 6

rulemaking by issuing a proposed rule, (iii) determined that the chemical poses an imminent hazard, but (iv) decided for whatever reason not to make the proposed rule immediately effective upon publication. None of those steps has occurred here.

Though ostensibly a mandatory duty, Section 7(a)(2) also imposes no deadline for EPA to act, opting instead for regulatory flexibility. *See Thomas*, 828 F.2d at 791 (explaining when a nondiscretionary duty exists). Appellants argue that a deadline can be inferred from Section 4(f) because Congress “would well have viewed” the 180-day deadline provided there, *see* 15 U.S.C. § 2603(f), “as a logical timeframe” for taking action under Section 7. Appellants’ Br. 53. That is incorrect. Not only is it “highly improbable that a deadline will ever be nondiscretionary, i.e., clear cut, if it exists only by reason of an inference drawn from the overall statutory framework,” *Thomas*, 828 F.2d at 791, but interpreting TSCA this way would impermissibly rewrite Section 4(f). By its terms, Section 4(f)’s obligations may be discharged by “initiat[ing] applicable action” under *either* “section 5, 6, *or* 7” of TSCA. 15 U.S.C. § 2603(f)(2). It does not follow that Section 4(f) also impliedly sets a deadline for initiating a mandatory action under Section 7. If anything, Section 4(f) makes clear that Congress knew how to impose a 180-day deadline when it intended to do so.

In support of their atextual reading, PEER and CEH turn to TSCA’s broader purpose. Appellants’ Br. 50–51. But as this Court has long recognized, purpose

cannot overcome the plain text of the statute. *See, e.g., Lindeen v. SEC*, 825 F.3d 646, 655 (D.C. Cir. 2016) (“[E]ven the most formidable argument concerning the statute's purposes [cannot] overcome the clarity [found] in the statute's text.” (second and third alteration in original) (quoting *Kloeckner v. Solis*, 568 U.S. 41, 55 n.4 (2012))). Nor does the legislative history PEER and CEH cite undermine the statute’s most natural reading. It too suggests that Congress intended to impose a nondiscretionary duty only when EPA elects not to “use[] the authority provided” in Section 6, H.R. Rep. No. 94-1679, to “declare a *proposed rule*” to be immediately effective. 15 U.S.C. § 2605(d)(3)(A)(i) (emphasis added). The legislative history does no more than confirm that the text means what it says: EPA “shall” bring an action only when the Administrator has not made a rule under Section 6(a) “immediately effective.” *Id.* § 2606(a)(2). Otherwise, it “may” commence a TSCA Section 7 action in its discretion. *Id.* § 2606(a)(1).

Indeed, as the District Court recognized, there are good reasons for Congress to have drafted the statute as it did. Construing Section 6 rulemaking as the trigger for any obligation to arise under Section 7(a)(2)—as the statute demands—ensures that EPA has undertaken the “careful consideration required by the statute’s rulemaking provisions” before taking draconian measures such as seizing property or shutting down a business or industry. JA205; *see also* 15 U.S.C. § 2605.

PEER and CEH’s interpretation would also entirely skip the need for EPA to make a preliminary determination that an imminent hazard exists. *See e.g., Friends of the Earth v. EPA*, 934 F. Supp. 2d 40, 48 (D.D.C. 2013) (reasoning that the “predicate for the mandatory duty” is “not the duty itself”); *see also id.* at 51 (“The finding or ‘judgment’ comes first, and it triggers the mandatory duty.”). Section 7 tasks *EPA* with deciding whether a chemical substance “presents an imminent and unreasonable risk of serious or widespread injury” that would occur “before a final rule under [Section 6] can protect against” it, and it gives EPA options for how to respond. 15 U.S.C. § 2606(f); *see id.* § 2606(a).

In Appellants’ view, however, TSCA authorizes citizen suits any time *any person* believes a chemical presents an unreasonable and imminent risk of harm—before EPA ever makes that determination. *See* Appellants’ Br. at 53–54 (arguing that PEER and CEH pled facts sufficient to state a claim). This approach would invite courts to substitute a plaintiff’s judgment for the agency’s, and it is not the scheme Congress created. *See Citizens for Responsibility & Ethics in Wash.*, 892 F.3d at 439 (noting “certain threshold legal determinations” must be made by the agency “in the first instance”); *see also Zook v. EPA*, 611 F. App’x 725, 726 (D.C. Cir. 2015) (explaining that “the plaintiffs are wrong in asserting that the Administrator has a nondiscretionary duty . . . without the agency having made the prerequisite determinations”).

To the extent Appellants argue that the text of Section 7 unambiguously requires EPA to make an imminent hazard finding, Appellants’ Br. 53-55, that is not a cognizable claim under the statute’s citizen-suit provisions. *Physicians Comm. for Responsible Med. v. Johnson*, 436 F.3d 326, 333–334 (2d Cir. 2006). An argument that “EPA *should* have made” an imminent-hazard finding “based on the evidence before it and [Appellants’] differing interpretation of the statute” must “be brought under the Administrative Procedure Act rather than this citizen-suit provision.” *Id.* (TSCA) (citing *Natural Res. Def. Council, Inc. v. Thomas*, 689 F. Supp. 246, 255 (S.D.N.Y. 1988) (rejecting a similar argument), *aff’d*, 885 F.2d 1067 (2d Cir. 1989)). Appellants, of course, have made no such claim.

Because TSCA did not require EPA to commence an action against Inhance under Section 7, PEER and CEH’s claim falls outside TSCA’s limited waiver of sovereign immunity to compel EPA to perform nondiscretionary duties. *See* 15 U.S.C. § 2619(a)(2); *Sierra Club v. Wheeler*, 956 F.3d 612, 618 (D.C. Cir. 2020) (upholding dismissal of citizen suit under the Clean Air Act for lack of subject matter jurisdiction). This Court should affirm the District Court’s judgment.

CONCLUSION

For the foregoing reasons, the District Court's judgment should be affirmed.

Respectfully submitted,

/s/ Jessica L. Ellsworth

JESSICA L. ELLSWORTH

SUSAN M. COOK

MARLAN GOLDEN

J. ANDREW MACKENZIE

HOGAN LOVELLS US LLP

555 Thirteenth Street, N.W.

Washington, D.C. 20004

(202) 637-5886

jessica.ellsworth@hoganlovells.com

J. TOM BOER

HOGAN LOVELLS US LLP

4 Embarcadero Center, Suite 3500

San Francisco, CA 94111

Phone: (415) 374-2336

Fax: (415) 374-2499

tom.boer@hoganlovells.com

Dated: August 29, 2025

Counsel for Inhance Technologies LLC

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(g)(1), the undersigned hereby certifies that this document complies with the type-volume limitation of D.C. Cir. R. 32(e)(2).

1. Exclusive of the exempted portions of the document, as provided in Fed. R. App. P. 32(f), this document contains 8,753 words.

2. The document has been prepared in proportionally spaced typeface using Microsoft Word in 14-point Times New Roman font. As permitted by Fed. R. App. P. 32(g)(1), the undersigned has relied upon the word count feature of this word processing system in preparing this certificate.

August 29, 2025

/s/ Jessica L. Ellsworth
Jessica L. Ellsworth

CERTIFICATE OF SERVICE

I certify that on August 29, 2025, the foregoing was electronically filed through this Court's CM/ECF system, which will send a notice of filing to all registered users.

/s/ Jessica L. Ellsworth
Jessica L. Ellsworth